REMARKS

Reconsideration of the present application in view of the above amendments and following remarks is respectfully requested. Claims 56-74 were pending. As set forth above, Applicants have canceled claims 60-64 and 69-73 without prejudice to the filing of any divisional, continuation, or continuation-in-part application, which is to merely expedite allowance of the subject application. Claim 56 has been hereby amended to more clearly define the subject matter encompassed by Applicants' invention, and claims 65 and 74 have been hereby amended for mere editorial purposes. Support for the amendment to claim 56 may be found in the subject application as originally filed, in part, at page 2, lines 13-23; at page 10, line 27 through page 11, line 15; and Figures 2-5. No new matter has been added. Therefore, claims 56-59, 65-68, and 74 are currently pending.

Undersigned representative for assignee wishes to thank Examiner Ford and Primary Examiner Navarro for a helpful telephonic discussion and suggestions on February 21, 2003.

REJECTION UNDER 35 U.S.C. §102(b)

In the Office Action dated October 22, 2002, claims 56-59, 65-68 and 74 were rejected under 35 U.S.C. §102(b) as unpatentable over WO 94/25598 (Kay *et al.*). In particular, it is alleged that Kay *et al.* teach *agfA* genes of *Salmonella* that have been engineered to contain foreign DNA encoding an epitope or antigen. It is further alleged that Kay *et al.* teach that the bacterial host cell that comprises the recombinant gene is able to express a stable *Salmonella* AgfA fimbrin protein fused to one or more foreign antigens.

Applicants respectfully traverse this ground of rejection and submit that Kay *et al.* fail to meet every limitation of the instant claims and, therefore, fail to anticipate the claimed invention. As described in the specification (*see, e.g.*, at page 2, lines 13-23) and recited in the claims, the present invention is directed to, in pertinent part, to a recombinant nucleic acid molecule that encodes a chimeric AgfA fimbrin polypeptide comprising at least one heterologous antigen, wherein said nucleic acid molecule encodes a chimeric polypeptide selected from the

group consisting of SEQ ID NO:12, SEQ ID NO:14, SEQ ID NO:16, SEQ ID NO:18, SEQ ID NO:20, SEQ ID NO:22, SEQ ID NO:24, SEQ ID NO:26, SEQ ID NO:28, and SEQ ID NO:30. Applicants respectfully submit that each of SEQ ID NOS:12, 14, 16, 18, 20, 22, 24, 26, 28, and 30 are all embodiments of a chimeric AgfA fimbrin polypeptide wherein the heterologous antigen is a PT3 epitope from GP63 of *Leishmania major* (*see, e.g.*, specification at page 3, lines 20-21) (*i.e.*, wherein at least one fimbrin polypeptide segment that is present in an AgfA polypeptide is replaced with a heterologous polypeptide antigen segment (PT3) that is equal in length to the AgfA polypeptide segment being replaced). Moreover, each of these chimeric fimbrin polypeptides is capable of forming fimbriae on the surface of a host cell expressing such chimeric AgfA polypeptides. Thus, the invention is also directed, in pertinent part, to a host cell that contains and expresses a recombinant nucleic acid molecule to produce a chimeric fimbrin polypeptide as set forth above and, further, produces stable fimbriae comprising the chimeric fimbrin polypeptide of the instant invention. As discussed in greater detail below, Applicants respectfully submit that Kay *et al.* fail to teach or suggest chimeric AgfA polypeptides according to the instant invention.

Kay *et al.* merely provide knock out mutants of the *agfA* gene to make attenuated *Salmonella* strains. That is, Kay *et al.* describe how to make *Salmonella* strains that no longer produce fimbriae. For example, Kay *et al.* provide afimbrial *Salmonella* strains by truncating *agfA* gene (*e.g.*, insertionally inactivated by an antibiotic resistance gene; *see* Kay *et al.* at page 40, Example 12), or by truncating the *agfA* gene through an insertion of the *phoA* gene (*see* Kay *et al.* at page 29, Example 3). Although Kay *et al.* mention that a fimbrin protein may be *fused* to a foreign antigen to elicit an immune response, no such fusion polypeptide to elicit an immune response is described. Moreover, the mutated *agfA* genes described by Kay *et al.* do not assemble into stable fimbriae because Kay *et al.* screened for the afimbrial phenotype. Hence, Kay *et al.* fail to provide every element of the instant claims and, therefore, fail to teach or suggest a chimeric AgfA fimbrin polypeptide according to the instant invention.

Accordingly, Applicants respectfully submit that the instant claims distinguish patentably over Kay *et al.* and, therefore, satisfy the requirements of 35 U.S.C. §102(b). Hence, Applicants request that this rejection be withdrawn.

The Commissioner is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

All of the claims pending (claims 56-59, 65-68, and 74) in the application are now clearly allowable. Favorable consideration and a Notice of Allowance are earnestly solicited. The Examiner is urged to contact the undersigned attorney if there are any questions prior to allowance of this matter.

Respectfully submitted,

Aaron P. White *et al.*

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